

REMARKS

Claims 1, 4, 6-12, and 16-18 are pending in this application after entrance of the above amendments, and Claims 2-3 and 13-15 are hereby cancelled. New Claims 17-18 are supported by the existing claims and do not introduce any new matter. Applicant appreciates the withdrawal of the prior rejections under 35 U.S.C. §112, second paragraph, and the acknowledgment of the corrected declaration.

Please note that a terminal disclaimer has been filed in U.S. application Number 07/958,426, filed October 8, 1992, in view of the present application.

Rejection under 35 U.S.C. §112, first paragraph

Claims 1-4 and 6-16 were rejected under 35 U.S.C. §112, first paragraph, as being non-enabled due to the claim term “glycolipid”. Applicant respectfully traverses.

First of all, Applicant has shown the efficacy of the ganglioside GD3, a glycolipid, to induce an immune response as evidenced by Livingston, et al. (Vaccine 11(12):1199-1204 (1993)), which was submitted with Applicant’s previous response. The Office appears to acknowledge that Livingston does exemplify an aspect of the claims. Therefore, the focus of the non-enablement rejection is based upon the scope of the claims versus the exemplification.

Applicant points out that the species utilized in Livingston is representative of the glycolipids as claimed. As stated in Applicant’s prior response on page 4, glycolipids have been defined as “a compound containing one or more monosaccharide residues bound by a glycosidic linkage to a hydrophobic moiety, such as an acylglycerol, a sphingoid, a ceramide, or a prenyl phosphate.” The exemplified ganglioside is distinguished from other glycolipids by its sphingoid moiety and sialic acid residue(s). All glycolipids have two saturated or unsaturated hydrocarbon chains comprising the hydrophobic moiety. Since the preparation of a proteosome vaccine depends on the hydrophobic moiety of the antigen to interact with the hydrophobic outer membrane proteins of the proteosomes, the hydrocarbon chains of the glycolipids are important. Since these hydrophobic chains are very similar and we have demonstrated with gangliosides that we can make

a vaccine that induces antibodies specific to the carbohydrate residue, gangliosides are representative of the family of glycolipids.

Second of all, since Applicant has disclosed at least one method/approach for using the claimed invention and that method has a reasonable correlation to the entire scope of the claims, then the enablement requirement of the statute is satisfied. See *In re Fisher* 166 USPQ 18, 24 (CCPA 1970). Moreover, Applicant respectfully submits that it is well established that an Applicant need not disclose every species encompassed by a claim (see *In re Angstadt* 190 USPQ 214, CCPA 1976). In the present situation, Applicant has shown an example of a glycolipid, which is the class of molecules claimed. One of skill in the art, from this teaching, would be able to substitute other glycolipids for the exemplified one and prepare and use the compositions and methods claimed. The glycolipids have similar properties and Applicant has shown the effectiveness of that class, thereby enabling the scope of the claims.

For these reasons, Applicant requests withdrawal of the 35 U.S.C. §112, first paragraph, rejection.

Rejections under 35 U.S.C. §112, second paragraph

Claims 1-4 and 6-16 were rejected under 35 U.S.C. §112, second paragraph, as indefinite due to certain terminology used in the claims. Applicant has modified a number of the claims as recommended by the Office and in some instances, the affected claims have been canceled. The helpful language suggestions by the Examiner are appreciated. For the record, however, Applicant asserts that the claim amendments are not made for the purposes of patentability and should not affect any future doctrine of equivalents analysis during patent enforcement. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, LTD 122 S.Ct.; 152 L. Ed. 2d 944; 62 USPQ2d 1705 (2002).

To assist the Examiner, Applicant discusses each particular rejection below. In Claim 1, the phrase “an effective amount” is allegedly indefinite. Although Applicant respectfully disagrees with the rejection, Claims 1 and 6 have been amended to remove the phrase and thus now renders the rejection moot.

Claims 2 and 3 were rejected but have been cancelled by the above amendment.

Claims 7-16 were rejected due to the phrases “providing enhanced immunogenicity”, “impart enhanced immunity”, “impart immunity”, “enhanced immunity” and “A method of inducing immunity”. At the Examiner’s kind suggestion, Applicant has amended these claims to describe inducing immunity. As a result, the rejections have been overcome and should be withdrawn.

Rejection under 35 U.S.C. §102(a)

Claims 1, 6-9 and 16 were rejected as anticipated by Livingston under 35 U.S.C. §102(a). Applicant respectfully traverses. The present application claims priority to October 29, 1993 via a PCT application through a series of continuation applications.

The Livingston reference was published sometime around October 1993, since it was received by the library at Washington State University Health Sciences on October 14, 1993. (See the attached correspondence.) Therefore, the Livingston reference was published less than one year before the present application’s priority date. Further, Dr. Lowell is the inventor of this application and is the last-listed author on the Livingston reference.

One aspect of §102(a) requires that the invention was known or used by others in this country. The courts have held that this knowledge or use must have been available to the public and not only to the inventor’s collaborators. Since the co-authors of Livingston were collaborating with the Applicant and they were not members of the general public for the purposes of §102(a), since they acquired their knowledge from the inventor. *See Woodland Trust v. Flowertree Nursery*, 47 USPQ2d 1363, 1365 (Fed. Cir. 1998).

Further, the knowledge of the collaborators did not occur prior to the invention as described in the application, which prior knowledge is required under 102(a), since they acquired knowledge from the inventor. For these reasons, Applicant asserts that the rejection under 35 USC §102(a) should be withdrawn.

However, in order to completely resolve this issue, Applicant submits the enclosed Declaration under 37 C.F.R. §1.132 explaining the contributions of the co-authors. *See In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 4060462000102. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Enclosures: Letter from Washington State University Health Sciences Library
Declaration of George H. Lowell, M.D. under 37 C.F.R. §1.132